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\*Admitted only in Maryland  
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\*Practice Limited to  
Federal Agencies

October 28, 2004

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Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**Mail Stop: Amendment**

Re: U.S. Utility Patent Application  
Appl. No.: 10/633,697; Filed: August 5, 2003  
For: **Glycosylation Engineering of Antibodies for Improving Antibody-  
Dependent Cellular Cytotoxicity**  
Inventors: Pablo UMAÑA *et al.*  
Our Ref: 1975.0010005/TJS/AWL

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement;
2. A listing of the cited documents on Form PTO-1449 (50 pages);
3. Copies of the cited documents (AL1, AR45 and AS45); and
4. One (1) return postcard.

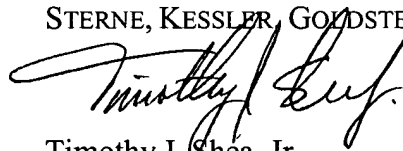
It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents  
October 28, 2004  
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Timothy J. Shea, Jr.  
Attorney for Applicants  
Registration No. 41,306

TJS/AWL:ddc  
Enclosures

327657\_1.DOC



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Pablo UMAÑA *et al.*

Appl. No.: 10/633,697

Filed: August 5, 2003

For: **Glycosylation Engineering of Antibodies  
for Improving Antibody-Dependent  
Cellular Cytotoxicity**

Confirmation No.: 5455

Art Unit: 1636

Examiner: Guzo, David

Atty. Docket: 1975.0010005/TJS/AWL

**Information Disclosure Statement**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of documents **AL1**, **AR45**, and **AS45** are included.

It is brought to the Examiner's attention that document **AL1**, PCT Patent Publication No. WO 94/11026, has replaced document **AN1**, European Patent Publication No. EP 0 669 836 B1, which was submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(b)(4) in Application No. 09/294,584, filed April 20, 1999.

A copy of documents **AA1** to **AK1** are not provided in accordance with the U.S. Patent and Trademark Office pre-OG notice of July 11, 2003, which states "[t]he Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003."

Copies of all other documents were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/294,584, filed April 20, 1999, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached under 37 C.F.R. § 1.98(d).

The Examiner's attention is directed to the following co-pending U.S. Patent Applications, which are directed to related technical subject matter: U.S. Patent Application No. 2004/0072290 A1, Umaña *et al.*, filed May 14, 2003 and cited herewith as document **AK1**; and U.S. Patent Application No. 10/633,699, Umaña *et al.*, filed August 5, 2003 and cited herewith as document **AR45**.

The identification of these U.S. Patent Applications is not to be construed as a waiver of secrecy as to these applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached Form PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may

not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

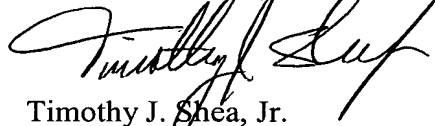
This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed Form PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Timothy J. Shea, Jr.  
Attorney for Applicants  
Registration No. 41,306

Date: October 28, 2004

1100 New York Avenue, N.W.  
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(202) 371-2600

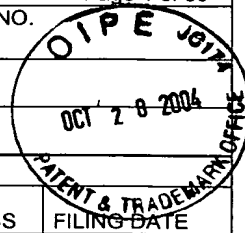
FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
1975.0010005/TJS  
FIRST NAMED INVENTOR  
Umaña *et al.*  
FILING DATE  
August 5, 2003

APPLICATION NO.  
10/633,697

ART UNIT  
1636

**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	4,215,051	07/29/1980	Schroeder <i>et al.</i>			08/29/1979
	AB1	4,946,778	08/07/1990	Ladner <i>et al.</i>			01/19/1989
	AC1	5,047,335	09/10/1991	Paulson <i>et al.</i>			12/21/1988
	AD1	5,547,933	08/20/1996	Lin			06/07/1995
	AE1	5,736,137	04/07/1998	Anderson <i>et al.</i>			11/03/1993
	AF1	5,776,456	07/07/1998	Anderson <i>et al.</i>			06/07/1995
	AG1	5,843,439	12/01/1998	Anderson <i>et al.</i>			06/07/1995
	AH1	5,952,203	09/14/1999	Withers <i>et al.</i>			04/11/1997
	AI1	5,958,403	09/28/1999	Strom <i>et al.</i>			07/11/1994
	AJ1	2003/0175884 A1	09/18/2003	Umaña <i>et al.</i>			08/05/2002
	AK1	2004/0072290 A1	04/15/2004	Umaña <i>et al.</i>			05/14/2003

**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	WO 94/11026	05/26/1994	WIPO			Yes No
	AM1	WO 95/24494	09/14/1995	WIPO			Yes No
	AN1	EP 0 669 836 B1	07/03/1996	Europe			Yes No
	AO1	EP 0 752 248 A1	01/08/1997	Europe			Yes No
	AP1	WO 97/30087	08/21/1997	WIPO			Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	1	Amstutz, H., <i>et al.</i> , "Production and Characterization of a Mouse/Human Chimeric Antibody Directed Against Human Neuroblastoma," <i>Int. J. Cancer</i> 53:147-152, Wiley-Liss, Inc. (1993)
	AS	1	Anderson, W.F., "Human gene therapy," <i>Nature</i> 392:25-30, Nature Pub. Co. (1998)
	AT	1	Arathoon, W.R., and Birch, J.R., "Large-Scale Cell Culture in Biotechnology," <i>Science</i> 232:1390-1395, American Association for the Advancement of Science (1986)

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes X No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>2</u>	Bailey, J.E., "Toward a Science of Metabolic Engineering," <i>Science</i> 252:1668-1675, American Association for the Advancement of Science (1991)
	AS	<u>2</u>	Bailey, J.E., <i>et. al.</i> , "Engineering Glycosylation in Animal Cells," in <i>New Developments and New Applications in Animal Cell Technology</i> , Merten, O.W., <i>et. al.</i> , eds., Kluwer Academic Publishers, The Netherlands, pp.5-23 (1998)
	AT	<u>2</u>	Bailey, J.E., <i>et. al.</i> , "Metabolic Engineering of N-Linked Glycoform Synthesis Systems in Chinese Hamster Ovary (CHO) Cells," in <i>Animal Cell Technology</i> , Carrondo, M.J.T., <i>et. al.</i> , eds., Kluwer Academic Publishers, The Netherlands, pp.489-494 (1997)

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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>3</u>	Bibila, T.A., and Flickinger, M.C., "A Model of Interorganelle Monoclonal Antibody Transport and Secretion in Mouse Hybridoma Cells," <i>Biotechnol. Bioeng.</i> 38:767-780, John Wiley & Sons, Inc. (1991)
	AS	<u>3</u>	Bibila, T.A., and Robinson, D.K., "In Pursuit of the Optimal Fed-Batch Process for Monoclonal Antibody Production," <i>Biotechnol. Prog.</i> 11:1-13, American Chemical Society and American Institute of Chemical Engineers (1995)
	AT	<u>3</u>	Bitter, G.A., "Heterologous Gene Expression in Yeast," <i>Meth. Enzymol.</i> 152:673-684, Academic Press, Inc. (1987)

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## FOREIGN PATENT DOCUMENTS

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>4</u>	Bitter, G.A., <i>et al.</i> , "Expression and Secretion Vectors for Yeast," <i>Meth. Enzymol.</i> 153:516-544, Academic Press, Inc. (1987)
	AS	<u>4</u>	Bretscher, M.S., and Munro, S., "Cholesterol and the Golgi Apparatus," <i>Science</i> 261:1280-1281, American Association for the Advancement of Science (1993)
	AT	<u>4</u>	Briles, E.B., <i>et al.</i> , "Isolation of Wheat Germ Agglutinin-resistant Clones of Chinese Hamster Ovary Cells Deficient in Membrane Sialic Acid and Galactose," <i>J. Biol. Chem.</i> 252:1107-1116, American Society for Biochemistry and Molecular Biology, Inc. (1977)

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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>5</u>	Brisson, N., <i>et al.</i> , "Expression of a bacterial gene in plants by using a viral vector," <i>Nature</i> 310:511-514, Nature Pub. Co. (1984)
	AS	<u>5</u>	Brockhausen, I., <i>et al.</i> , "Control of glycoprotein synthesis. Characterization of (1 4)-N-acetyl-β-D-glucosaminyltransferases acting on the α-D-(1 3)- and α-D-(1 6)-linked arms of N-linked oligosaccharides," <i>Carbohydrate Res.</i> 236:281-299, Elsevier Science Publishers B.V. (1992)
	AT	<u>5</u>	Brogliè, R., <i>et al.</i> , "Light-Regulated Expression of a Pea Ribulose-1,5-Biphosphate Carboxylase Small Subunit Gene in Transformed Plant Cells," <i>Science</i> 224:838-843, American Association for the Advancement of Science (1984)

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	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>6</u>	Campbell, C., and Stanley, P., "A Dominant Mutation to Ricin Resistance in Chinese Hamster Ovary Cells Induces UDP-GlcNAc:Glycopeptide $\beta$ -4-N-Acetylglucosaminyltransferase III Activity," <i>J. Biol. Chem.</i> 261:13370-13378, American Society for Biochemistry and Molecular Biology, Inc. (1984)
	AS	<u>6</u>	Caruthers, M.H., <i>et al.</i> , "New chemical methods for synthesizing polynucleotides," <i>Nuc. Acids Res. Symp. Series</i> 7:215-223, IRL Press Limited (1980)
	AT	<u>6</u>	Chow, F., <i>et al.</i> , "Synthesis of oligodeoxyribonucleotides on silica del support," <i>Nuc. Acids Res.</i> 9:2807-2817, IRL Press Limited (1981)

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	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>7</u>	Cole, N.B., <i>et al.</i> , "Diffusional Mobility of Golgi Proteins in Membranes of Living Cells," <i>Science</i> 273:797-801, American Association for the Advancement of Science (1996)
	AS	<u>7</u>	Cole, S.P.C., <i>et al.</i> , "The EBV-Hybridoma Technique and its Application to Human Lung Cancer," in <i>Monoclonal Antibodies and Cancer Therapy</i> , Reisfeld, R.A., and Sell, S., eds., Alan R. Liss, Inc., New York, NY, pp.77-96 (1985)
	AT	<u>7</u>	Coruzzi, G., <i>et al.</i> , "Tissue-specific and light-regulated expression of a pea nuclear gene encoding the small subunit of ribulose-1,5-biphosphate carboxylase," <i>EMBO J.</i> 3:1671-1679, IRL Press Limited (1984)

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	AO						Yes No
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**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	<u>8</u>	Cote, R.J., <i>et. al.</i> , "Generation of human monoclonal antibodies reactive with cellular antigens," <i>Proc. Natl. Acad. Sci.</i> 80:2026-2030, The National Academy of Sciences (1983)
AS	<u>8</u>	Crea, R., and Horn, T., "Synthesis of oligonucleotides on cellulose by a phosphotriester method," <i>Nuc. Acids Res.</i> 8:2331-2348, IRL Press Limited (1980)
AT	<u>8</u>	Creighton, T.E., <i>Proteins: Structures and Molecular Principles</i> , W.H. Freeman and Co., New York, NY, pp.34-60 (1983)

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	AN						Yes No
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**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	<u>9</u>	Cumming, D.A., "Glycosylation of recombinant protein therapeutics: control and functional implications," <i>Glycobiology</i> 1:115-130, Oxford University Press (1991)
AS	<u>9</u>	Dörr, U., <i>et al.</i> , "First Clinical Results with the Chimeric Antibody chCE7 in Neuroblastoma. Targeting Features and Biodistribution Data," <i>Eur. J. Nucl. Med.</i> 20:858, Springer International (1993)
AT	<u>9</u>	Dennis, J.W., <i>et al.</i> , "β1-6 Branching of Asn-Linked Oligosaccharides Is Directly Associated with Metastasis," <i>Science</i> 236:582-585, American Association for the Advancement of Science (1987)

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	AR	<u>10</u>	Do, K.-Y., "Modification of Glycoproteins by N-Acetylglucosaminyltransferase V Is Greatly Influenced by Accessibility of the Enzyme to Oligosaccharide Acceptors," <i>J. Biol. Chem.</i> 269:23456-23464, American Society for Biochemistry and Molecular Biology (1994)
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AR	<u>12</u>	Elices, M.J., and Goldstein, I.J., "Ehrlich Ascites Tumor Cell UDP-Gal:N-Acetyl-D-glucosamine $\beta$ (1,4)-Galactosyltransferase," <i>J. Biol. Chem.</i> 263:3354-3362, American Society for Biochemistry and Molecular Biology, Inc. (1988)
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AR	<u>13</u>	Field, M., <i>et al.</i> , "The Use of High-Performance Anion-Exchange Chromatography and Matrix-Assisted Laser Desorption/Ionization Time-of-Flight Mass Spectrometry to Monitor and Identify Oligosaccharide Degradation," <i>Anal. Biochem.</i> 239:92-98, Academic Press, Inc. (1996)
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AR	<u>19</u>	Jenkins, N., and Curling, E.M.A., "Glycosylation of recombinant proteins: Problems and prospects," <i>Enzyme Microb. Technol.</i> 16:354-364, Butterworth-Heinemann (1994)
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	AM						Yes No
	AN						Yes No
	AO						Yes No
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**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>23</u>	Lund, J., <i>et al.</i> , "Control of IgG/Fc Glycosylation: A Comparison of Oligosaccharides from Chimeric Human/Mouse and Mouse Subclass Immunoglobulin Gs," <i>Molec. Immunol.</i> 30:741-748, Pergamon Press Ltd. (1993)
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	AT	<u>23</u>	Malhotra, R., <i>et al.</i> , "Glycosylation changes of IgG associated with rheumatoid arthritis can activate complement via the mannose-binding protein," <i>Nat. Med.</i> 1:237-243, Nature Pub. Co. (1995)

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AR	<u>24</u>	Marshall, E., "Gene therapy's growing pains," <i>Science</i> 269:1050-1055, American Association for the Advancement of Science (1995)
AS	<u>24</u>	Matteucci, M.D., and Caruthers, M.H., "The Synthesis of Oligodeoxypyrimidines on a Polymer Support," <i>Tetrahedron Letters</i> 21:719-722, Pergamon Press Ltd. (1980)
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	AR	<u>25</u>	Moremen, K.W., <i>et al.</i> , "Glycosidases of the asparagine-linked oligosaccharide processing pathway," <i>Glycobiology</i> 4:113-125, Oxford University Press (1994)
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	AR	<u>26</u>	Narasimhan, S., "Control of Glycoprotein Synthesis," <i>J. Biol. Chem.</i> 257:10235-10242, American Society for Biochemistry and Molecular Biology, Inc. (1982)
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AS	<u>27</u>	Nilsson, T., et. al., "Kin recognition between <i>medial</i> Golgi enzymes in HeLa cells," <i>EMBO J.</i> 13:562-574, Oxford University Press (1994)
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AR	<u>28</u>	Nilsson, T., <i>et al.</i> , "The role of the membrane-spanning domain and stalk region of <i>N</i> -acetylglucosaminyltransferase I in retention, kin recognition and structural maintenance of the Golgi apparatus in HeLa cells," <i>J. Cell Sci.</i> 109:1975-1989, The Company of Biologists Limited (1996)
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	AR	<u>29</u>	Orkin, S.H. and Motulsky, A.G., "Report and recommendations of the panel to assess the NIH investment in research on gene therapy," December 7, 1995, available at < <a href="http://www.nih.gov/news/panelrep.html">http://www.nih.gov/news/panelrep.html</a> >
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	AT	<u>29</u>	Page, M.J., and Sydenham, M.A., "High Level Expression of the Humanized Monoclonal Antibody CAMPATH-1H in Chinese Hamster Ovary Cells," <i>Biotechnology</i> 9:64-68, Nature Pub. Co. (1991)

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	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>30</u>	Palcic, M.M., <i>et al.</i> , "Regulation of N-Acetylglucosaminyltransferase V Activity," <i>J. Biol. Chem.</i> 265:6759-6769, American Society for Biochemistry and Molecular Biology, Inc. (1990)
	AS	<u>30</u>	Paulson, J.C., and Colley, K.J., "Glycosyltransferases," <i>J. Biol. Chem.</i> 264:17615-17618, American Society for Biochemistry and Molecular Biology, Inc. (1989)
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	AR	<u>31</u>	Rabouille, C., <i>et al.</i> , "Mapping the distribution of Golgi enzymes involved in the construction of complex oligosaccharides," <i>J. Cell Sci.</i> 108:1617-1627, The Company of Biologists Limited (1995)
	AS	<u>31</u>	Rao, A.K., and Mendicino, J., "Influence of Glycopeptide Structure on the Regulation of Galactosyltransferase Activity," <i>Biochem.</i> 17:5632-5638, American Chemical Society (1978)
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	FIRST NAMED INVENTOR Umaña <i>et al.</i>	
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